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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,786	06/05/2006	Gerard Cousin	065691-0432	3644

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,786	COUSIN ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *10-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 January 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/17/2006, 4/10/2006, 6/5/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-17 are currently pending.

Election/Restrictions

Applicants' election of group I drawn to method of preparing a particle composition, in the reply filed on 11/13/2008 is acknowledged.

The election was made with traverse on the ground that Groups I and II are related to a single general inventive concept under PCT Rule 13.1 since the common technical feature between Groups I and I1 is the claimed process of claims 1-9 and U.S. Patent No. 6,027,747 cited fails to disclose the process of claims 1-9.

This is not found to be persuasive. As stated in the previous action mailed on 10/15/2008, the common technical feature between Groups I and II is a particle composition recited in the claim 10, which is shown in US patent 6,027,747, thus there is no special technical feature shared by groups I and II and as such, unity between the above Groups I and II is broken.

The requirement is still deemed proper and is therefore made final.

Claims 10-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Claims 1-9 are under examination in the instant office action.

Priority

The instant application is a 371 of PCT/FR04/01878 filed on 7/16/2004 and claims benefit of foreign applications filed on 7/17/2003. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of foreign application has been submitted on 1/17/2006.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 7/16/2004.

Information Disclosure Statement (IDS)

Signed and initialed copies of the information disclosure statements filed on 4/10/2006 and 6/5/2006 are enclosed in this action. The IDS filed on 1/17/2006 is not considered since it lists the same references as the IDS filed on 4/10/2006.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5-6, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation following the phrase is part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,027,747 (Issue date: 2/22/2000) in view of Us patent 4,016,254 (Issue Date: 4/5/1977).

US 6,027,747 teaches a solid dispersion of at least one therapeutic agent preferably hardly water-soluble active ingredients in a hydrophilic carrier, made by the process comprising dissolving at least one therapeutic agent in a volatile organic solvent with a hydrophilic polymer such as polyvinylpyrrolidone, and evaporating the solvent to dryness to form a co-precipitate of therapeutic agent and hydrophilic polymer (abstract, column 3, line 49-column 4, line 8, and column 7, lines 50-column 8, line 8) and this process provide a novel process for dry pharmaceutical products and the co-precipitate formed thereby which has faster and greater resorption when administered orally (column 2, lines 17-20). It further teaches that a surface-

active agent such as non-ionic surface agent is further added (column 3, lines 33-38) and the organic solvent is selected from ethanol, isopropanol, tetrahydrofuran, isopropyl ether, acetone, methy ethyl ketone, tetrahydropyran, or chlorinated solvents such as methylene chloride or even mixtures in various proportions of these same solvents (coumn 3, lines 21-31). In addition, US 6,027,747 discloses that the coprecipitates comprising fenofibrate (active substance), poyvinylpyrrolidone (hydrophilic polymer), and Tween 80 (surface-active agent) dissolved in absolute ethanol are sprayed on neutral pellets of carbohydrates (neutral hydrophilic carrier) such as levulose, lactose, arabinose mannose, sorbose, cellulose and its derivatives, starch, dextrins and the like, and the sprayed granules are dried on a fluidized bed dryer (column 19, line 20-column 20, line 6 and claim 2).

The reference differs from the instant invention insofar as it does not state milling step and the repetition of spraying and milling.

Us patent 4,016,254 teaches that the processing of medicaments from the initial production of the compound to the formulated product ready for use normally involves a milling stage, and further teaches that milling is included to reduce the particle size of the medicament, to improve the drying rate of the material, to aid in blending operations, to increase the bioavailability of the medicament from the formulation or for various other reasons (column 1, lines 56-63).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made to repeat spraying and milling steps for the process of making a particle as taught by US 6,027,747 since the person skilled in the art would have expected that the repetition of spraying and milling steps ensures the particles to possess adequate amount of

active substance as well as even distribution and to have an optimum particle size for bioavailability and absorption in view of teachings of Us patent 4,016,254 and US 6,027,747.

In the alternative, when the prior art already teaches an almost identical process of making particles using the same ingredients, adding spraying and milling steps one or more times, which are well-known process in the pharmaceutical art, would be obvious and not considered to be inventive, unless the applicants present data showing that the process having the claimed feature (repetition of spraying and milling) provides unexpected properties or effect on the resulting product compared to the process of US 6,027,747.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/564845. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application 10/564845 anticipate the instant claims. The claims of copending Application No. 10/564845 are drawn a process of making a particle composition comprising a specific active substance such as antiviral pyrimidine or triazine while the instant claims are drawn to the same process of making a particle composition containing any active substance. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slater*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gustily*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gustily claimed a genus of 21 specific chemical species of bicyclical thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed

that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614

BONG-SOOK BAEK
Examiner, Art Unit 4161

Bbs